Improvements in Quality Control Systems for Detecting Leaks of Gaseous or Liquid Materials from Closed Containers

This application is a continuation-in-part of prior provisional application U.S.S.N. 60/291,876, which was filed on May 18, 2001, and claims priority under 35 U.S.C. §119 therefrom.

BACKGROUND OF THE INVENTION

Plants and systems for testing whether a hollow body encasing gases or liquids (usually under pressure) is leaktight often operate according to the pressure maintaining principle. Here, the hollow body which is to be tested is surrounded with a vacuum. If the vacuum remains constant over the test period, the hollow body is considered leaktight. However, if the vacuum decreases and the pressure increases beyond a pre-determined fixed value, the hollow body is considered to be leaky.

Containers or cartridges for medical fluids or dosing aerosols for inhalers are named as examples of test subjects from the field of medicine. For example, reference is made to documents EP 0 775 076 B1, WO 00/49988, WO 97/39831 and WP 00/23037. All of the cartridges or containers described therein must be tested for their leaktightness. The methods used to this end include systems employing the hereinbefore-mentioned pressure-maintaining principle. The disclosures of such publications are herein incorporated by reference.

In order to guarantee the continuity of the test process, it is necessary to test the system itself via which the leaktightness of the hollow body is checked. An examination is carried out as to whether the measured pressure increase due to leakage is accurately measured and whether the correct conclusions are drawn from the measured values. It is therefore necessary to subject the leaktightness testing system itself to an examination from time to time.

In accordance with this, it is the object of the present invention to specify an examination system for such a leaktightness testing system.

THE INVENTION

In systems for testing hollow bodies, e.g., medical cannisters, to determine whether such cannisters or bodies are leaky, the cannister or hollow body (filled with gas or liquid) is placed in a vacuum. If the vacuum remains constant over a specified test period, then the cannister or hollow body is deemed leak-tight. However, if the vacuum decreases and the pressure increases beyond a pre-determined value, then the hollow body or cannister can be considered to be leaky. These systems must also undergo integrity checks. Accordingly, the present inventor has determined that the integrity of such systems can be ascertained by using, in place of the hollow body or cannister, a test body having certain characteristics. These characteristics allow reliable statements to be made as to whether the leaktightness testing system is functioning correctly.

This object is solved by the system according to the present invention, making reference to the drawings appended hereto.

Consequently, according to the first solution suggestion, a system for testing systems which in turn are used to check that a hollow body is leaktight is suggested wherein instead of the actual hollow body which is to be tested for leaktightness, a test body is placed in a test chamber which is separated into two chambers in such a way that one portion of the test body is exposed to the first chamber, which is at ambient pressure, and another portion of the test body is exposed to the second chamber which is at reduced air pressure. Here, the two chambers are separated from one another by means of a seal. The test body extends in a sealing manner through a penetration in the seal. Hence it is ensured that both chambers are separated from one another with regard to pressure. The test body has a defined leakage with a pre-specified leakage rate which corresponds to the amount of leakage which is still just acceptable in order for the hollow body to be defined as leaktight. As a result of the defined leakage, there is now a pressure increase in the second chamber which has lower air pressure. This pressure increase is measured over a certain

period of time. If the measured leakage rate exceeds the pre-specified maximum leakage rate, it can be concluded that the entire system is not functioning correctly, since an additional leak must have appeared in the system or the measuring apparatus must not be functioning correctly. The operating personnel of the leaktightness testing system can then implement suitable measures to return the leaktightness testing system to its proper working condition.

A test body according to the invention for use in the hereinbefore-described system is configured so that the pre-specified leakage is realized by a glass capillary of given length and given diameter. This glass capillary therefore penetrates the hereinbefore--described seal between the two chambers of the test chamber which have different air pressures. Correspondingly, the glass capillary simulates a hollow body, for example a cartridge according to the above documents, with maximum tolerable leakage. Here, in a special application case the leakage rate of the glass capillary is 6.67×10^{-3} mbar/sec x_1 for ambient atmosphere (ambient air).

This value corresponds to the maximum tolerable value for the cartridges or hollow bodies.

For reasons of practicality, the glass capillary is preferably supported by a sealed hollow body.

The given leakage of the glass fibres is preferably pre-specified by the diameter of the capillary, which, for this example, lies in the range of max. 50 μm.

According to the second embodiment of the present invention, a system is provided for the testing of *systems which in turn* are used to check that a *hollow* body is leaktight wherein instead of the hollow body, a test body is placed in a vacuum chamber, wherein a defined amount of moistness is supplied to the test body in advance and an increase in pressure is measured in the vacuum chamber within a pre-determined time span. If this measured pressure increase exceeds a given maximum pressure increase, it can be assumed that the leaktightness testing system is faulty.

The basis for this system is that the test body comprises a material which can absorb a defined amount of moistness from the ambient atmosphere during storage. The quantity of absorbable moistness can, among other things, be influenced by the size of the surface of the test body.

A vacuum is now generated around the test body in the vacuum chamber. During the test period, moisture is removed from the test body and is evaporated at least in part in the vacuum. This evaporation increases the pressure in the vacuum chamber. Dependent on the time span and the quantity of absorbed moisture, a defined pressure rise in the vacuum chamber is produced. This correlates with a just-tolerable pressure rise in the hollow body which is to be tested for leaktightness, the actual test subject of the leaktightness testing system.

Common to both systems is that the actual leaktightness testing system is calibrated in that the just-tolerable leakages are simulated, and in the actual test process. Exceeding those pre-determined parameters is a clear indication of additional leakages or other failures in the system function.

As already mentioned, in the case of the system according to the second embodiment, the test body comprises a special material. Materials to be used are those which have a relatively high absorbency capacity for moisture. The use of polyamide or polyoxymethyl is preferred.

A great advantage of all suggested test bodies is that these can be re-used after a recovery time. In the case of the system according to the first solution suggestion, pressure equilibration with the surroundings takes place during the recovery time after the test. In the case of the system according to the second solution suggestion, renewed absorption of moisture from the surroundings, with climate being constant, takes place after the test.

The invention is described with reference to two examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 schematically, the system according to the first embodiment,

Fig. 2 the system according to the first embodiment, ready to use,

Fig. 3 the system of Fig. 2 during the test, and

Fig. 4 the system according to the second embodiment.

DETAILED DESCRIPTION OF THE DRAWINGS

In the following text, the same reference numerals designate identical parts.

Fig. 1 schematically shows the first system. It substantially comprises the test chamber 5 in which the actual test subject, namely the hollow body, is placed after the leaktightness testing system has been recognized as ready to use. However, in order to test this system, the test body 2 is used. The test body 2 extends through a seal 6 via which the lower part of the test chamber 5 is sealed, separating off a first test chamber 3 which is generally at ambient pressure.

In the present case, the test body 2 comprises a hollow body and a defined leak which is realized by a glass capillary 7 of given length and given diameter. In order to implement the test, a suction vessel 8 is placed on the seal 6 and the thus-defined space is evacuated until the pressure therein is approximately 1 mbar. The suction vessel 8 encloses the second chamber 4 of the test chamber 5. If the air pressure in the first chamber 3 is approximately 1000 mbar and is approximately 1 mbar in the second chamber 4, the pressure difference between the two chambers is 999 mbar. Together with the glass capillary 7 of the test body 2, a certain pressure equilibration takes place between the chambers 3 and 4 within a given period of time. This is shown schematically in Fig. 3, where the air stream through the glass capillary 7 is indicated by the arrow 9.

The dimensions of the glass capillary 7 are selected so that the leakage rate corresponds to a leakage rate which indicates that the leakage is just acceptable in the case of the hollow body which is to be tested.

The leakage rate is determined by seniors (not illustrated). If the leakage rate exceeds a given value, it can be inferred that the system as such does not comply with the requirements for further use in the leaktightness testing process. Additional leakage is then the main cause of faulty function.

Fig. 4 schematically shows the second suggested system. A test body 20 is placed in a vacuum chamber 20. A vacuum is generated around this test body in the vacuum chamber 30. Following this, moisture is withdrawn from the test body 20 during the test phase and is at least partially evaporated in the vacuum. This evaporation increases the pressure in the vacuum chamber 30, which can be measured by sensors (not illustrated). This rise in pressure corresponds to that which is just tolerable in the case of hollow bodies which are to be tested in the leaktightness testing system for their leaktightness.